Citation:

Schaffner DW, Schaffner KM. Management of risk of microbial cross-contamination from uncooked frozen hamburgers by alcohol-based hand sanitizer. *J Food Prot*. 2007; 70: 109-113

PubMed ID: 17265868

Study Design:

Laboratory and computer simulations

Class:

D - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To determine the effectiveness of an alcohol-based hand sanitizer on hands contaminated with a non-pathogen surrogate for *Escherichia coli* (E. coli) O157:H7
- To model the effectiveness of this intervention relative to other possible interventions.

Inclusion Criteria:

Rutgers University staff members and students.

Exclusion Criteria:

Not a Rutgers University staff member and student.

Description of Study Protocol:

Recruitment

Not available

Design

- Experiment
  - Frozen hamburger patties (76% lean beef and 24% fat) were inoculated by a non-pathogenic nalidixic acid-resistant Enterobacter aerogenes (*E. aerogenes*)
  - Each participant handled (stacking and unstacking) nine patties at least three times
  - Participants rated the perceived level of food debris on their hands on a five-point scale in every experiment
  - The investigators noted whether the hands appeared to contain visible debris from the burgers

- A sample for microbiological analysis was collected from the surface of one hand via the glove juice method
- The participants sanitized both hands using an alcohol-based hand sanitizer
- A sample was collected from the other hand via the glove juice method
- The collected samples were diluted as needed and spread plated (0.1ml) and pour plated (1.0ml) on MacConkey agar with 50μg/ml nalidixic acid
- For direct comparison of the behavior of *E. coli* O157:H7 vs. *E. aerogenes*, they were inoculated (0.25ml each) onto each side of nine hamburgers patties and the experiment proceeded with a single participant
- Control experiments included recovery of both organisms from inoculated burgers and from both sanitized and unsanitized hands
- Approximately 24 hours later, the experiment was repeated to determine whether the organisms persisted on the participant's hands

- Simulation
  - The real-world risk estimation calculations were carried out based on the actual prevalence and concentration of *E. coli* O157:H7 in ground beef, assuming
    - A single cell has a volume of approximately 1 μm3
    - Each burger contains 100,000 colony forming unites (CFU) of *E. coli* O157:H7, all located on the burger surface
    - An individual would handle 27 hamburger patties and then a handle a single piece of lettuce
  - Worse-case simulations were carried out with the assumptions above except the second assumption.

Dietary Intake/Dietary Assessment Methodology

Not applicable

Blinding used

Not applicable

Intervention

- The sanitizer used for the experiment: applied approximately 1ml of alcohol-based hand sanitizer (60% ethanol plus inactive ingredients) on contaminated hands until the participant determined the process was complete (generally less than 30 seconds)
- Other interventions (hand washing, glove use) for the computer simulations (based on data presented elsewhere).

Statistical Analysis

- Log transfer rates of *E. aerogenes* from frozen hamburgers to hands were calculated
- Log reduction in *E. aerogenes* concentration after using the sanitizer was calculated
- Concentration of *E. coli* O157:H7 per lettuce leaf after handling raw hamburgers was calculated for different interventions and no intervention (based on data presented elsewhere except for the sanitizer intervention)
- Log transfer rates and sanitizer log reductions were assumed to be normally distributed.

Data Collection Summary:

Timing of Measurements

Before and after using an hand sanitizer (for experiment)

Dependent Variables

- Change in concentration of *E. aerogenes* deposited on hands before and after the use of an hand sanitizer (for experiments)
- Concentration of *E. coli* O157:H7 per lettuce leaf after handling raw hamburgers (for simulations).

Independent Variables

- The sanitizer intervention (for experiments)
- Other interventions (hand washing, glove use) (for simulations).

Control Variables

- Control experiments (recovery of both organisms from inoculated burgers and from both sanitized and unsanitized hands) (for the direct comparison of *E. aerogenes* and *E. coli* O157:H7)
- No intervention (for simulations).

Description of Actual Data Sample:

- **Initial N:** 32 participants
  - 12 males
  - 20 females
- ***Attrition (final N):*** 32
- ***Age:*** Not available
- **Ethnicity**: Not available
- **Other relevant demographics:** University staff members and students
- ***Anthropometrics:*** Not applicable
- ***Location:*** Rutgers University, New Brunswick, New Jersey, USA.

Summary of Results:

Findings from the experiment

- The average transfer rate of *E. aerogenes* from frozen hamburgers to hands was 1.48%, which corresponds to a 1.83 log CFU reduction with ±0.70 log CFU variability per hand
- The average reduction of *E. aerogenes* after using the sanitizer was 2.58 log CFU with ±0.65 log CFU variability per hand.

Findings from the simulation

- The risk estimation for transfer of *E. coli* O157:H7 to a single piece of lettuce is 10-6 CFU per lettuce leaf
- None of the interventions (hand washing, gloves, sanitizer) were completely effective
- All interventions were more effective than no intervention at all
  - The mean reduction for hand washing and the use of gloves or sanitizer was about 3 log (1,000 times) greater than the result for no intervention at all

- The three interventions appear to have similar effectiveness, with an average simulated *E. coli* O157:H7 concentration of 10-2 CFU per lettuce leaf
- The minimum reduction using gloves or sanitizer was about 2 log greater than that for either no intervention or hand washing
- The effectiveness of an alcohol-based hand sanitizer to prevent transfer of *Enterobacter aerogenes* from frozen hamburger beef patties (inoculated with this non-pathogenic strain used as a surrogate for *Escherichia coli* O157:H7) to ready to lettuce was similar to the one previously found by the same group for hand washing with soap or glove use.

Author Conclusion:

- The risk of contamination of ready-to-eat food through transfer of *E. coli* O157:H7 from frozen hamburgers is very, very low, even when no intervention is used
- Use of an alcohol-based hand sanitizing gel is an effective intervention for hands that have been contaminated with *E. coli* O157:H7 from frozen hamburgers
- The results suggest that because the variability in the effectiveness of the hand sanitizer is less than the variability of the hand washing process, the minimally effective application of hand sanitizer is more effective than minimally effective hand washing due to lesser variability in the effectiveness of the hand sanitizer than the hand washing
- The finding of no significant differences in sanitizer effectiveness against *E. coli* O157:H7 and an enteric pathogen surrogate could be helpful for managing the risk of transfer of other enteric pathogens such as Salmonella, Campylobacter and some viruses.

Reviewer Comments:

The authors noted the following limitation:

- *If the frozen burgers were allowed to thaw (even only at the surface), transfer rates (and risk) might be expected to rise by an order of magnitude because moisture facilitates microbial transfer (and the investigators noted that most of the subjects had visible debris on their hands after handling the frozen burgers)*
- *In some experiments of the present study, participants handled up to 10 sets of uninoculated patties before handling inoculated patties to increase potential levels of food debris on the hands. Because no significant differences in bacterial transfer between the two, results from both portions of the experiment were combined.*
- *The effect of sanitizer on E. aerogenes and E. coli O157:H7 were tested via coinoculating both organisms due to large variability between replicates for a valid comparison.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes

2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	No
2.2.	Were criteria applied equally to all study groups?	N/A
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	???
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	???
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	N/A
4.1.	Were follow-up methods described and the same for all groups?	N/A
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	N/A
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	N/A
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	N/A
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	N/A
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
8.6.	Was clinical significance as well as statistical significance reported?	N/A
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes